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June 10, 2005

Commissioner Robert E. Nicolay, CPA
Chairman, CON Task Force
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

RE: Comments to CON Task Force

Dear Commissioner Nicolay:

Southern Maryland Hospital Center ("SMHC") respectfully submits the following comments to the Certificate of Need ("CON") Task Force.

First, SMHC endorses and agrees with the comments submitted by the Maryland Hospital Association CON Work Group.

Second, SMHC submits that there are three overarching questions facing the Task Force:

(1) Which healthcare services and expenditures should be subject to CON regulation?

(2) How can the CON process be made more efficient and effective?

(3) How can the CON process improve the healthcare system, especially by reducing racial disparities in healthcare?

In general, SMHC believes that the Health Care Commission should be guided by what we call "market-focused health planning". That is, if a service or expenditure can be adequately regulated by market forces, it should be freed from CON regulation and the marketplace should provide the necessary checks and balances. And if a service or expenditure requires CON regulation, the CON process should attempt to emulate marketplace forces to the extent possible by incorporating market data into its health planning and CON decisions. We provide examples of this in the discussion that follows.

1. Which Services/Expenditures should be regulated?

SMHC believes that the "core" of facility-based healthcare services should continue to be subject to CON regulation. This consists of:

- New hospitals
- New nursing homes
- New hospital beds in excess of the Maryland licensed-bed formula (140% of prior year's average daily census)
- New operating rooms in both hospitals and ambulatory surgery centers ("ASCs")
- New tertiary services (open heart surgery, organ transplantation, neonatal intensive care, and burn centers)
- New medical services (medical-surgical, obstetrical, pediatrics and psychiatric)

The reasons for continued CON regulation of these core services include cost control in the case of new facilities – the Health Services Cost Review Commission ("HSCRC") does an excellent job of regulating prices of existing hospital services, but once a new facility or service is created, it must approve reasonable rates regardless of whether additional services are needed or demanded by the marketplace – and quality concerns in the case of tertiary services – it has been well established that low-volume providers of tertiary care tend to provide lower-quality services, and having too many programs would lead to low-volume providers.

However, beyond this "core" of facility-based services, market forces should be given a free hand or incorporated into the regulatory process. A prime example is Maryland's annual relicensure formula applied to hospital beds, in which the number of licensed beds at a hospital is fixed at 140% of the average daily census during the prior year. This allows the marketplace, as expressed by the demand for hospital beds, to determine the supply of licensed beds. This market-focused regulatory mechanism largely replaces the traditional health planning approach of attempting to forecast future need, which is a very difficult task.

Certain services which are now regulated by CON could be better regulated by the marketplace. One example is home health and hospice services, which do not require large capital expenditures and whose costs are well contained by third-party reimbursement. (SMHC is itself a provider of home health services via its affiliate, Southern Maryland Home Health Services, Inc., but it believes that protectionism is not a sufficient justification for CON regulation.)

SMHC also submits that capital expenditures for information technology ("IT") should no longer be subject to CON regulation. (The current CON law exempts IT only if it is unrelated to patient care.) Unlike new medical services, which generate additional

reimbursement, there is no financial incentive for hospitals to spend money on IT systems – unless they actually save money through efficiencies or improve the quality of services (by reducing errors in patient medication, for example). Thus, IT expenditures should be regulated by the marketplace and not through the CON process.

SMHC also believes that the capital expenditure threshold for facility improvements/expansions/renovations should be increased to at least $10 million, or else capital expenditures should be completely deregulated. (The construction of new healthcare facilities or expansion of bed capacity beyond the licensure formula should still be subject to CON regulation independent of capital expenditures.) The HSCRC already regulates the reasonableness of hospital rates, including the capital cost component of those rates. CON regulation is particularly hard to justify in the case of relatively small projects, which have minimal impact on costs and rates. The cost and delay of the CON process pose substantial barriers to the renovation and expansion of hospitals, particularly in the case of smaller projects in the range of $1.6 million to $10 million.

SMHC also agrees with the MHA Work Group that the MHCC should be more flexible in approving "shell space" as part of major hospital renovation projects. It is economically efficient to build in some extra space for future uses as part of a large renovation project.

SMHC submits that hospitals should be allowed the flexibility to relocate existing beds and services within their primary service areas, including the relocation of hospital operating rooms to ambulatory surgery centers, without CON approval. This is an example of market-focused health planning. The marketplace determines the geographic area within which a hospital provides services to patients. If a hospital wants to relocate existing beds or services within the area in which it already serves, it should be free to do so. The only relevant change is the capital expenditure, which would be subject to review in its own right (unless all capital expenditures are deregulated), and which will in any event be regulated by the HSCRC and by third-party payers.

The relocation of existing services within a primary service area should be subject to some limitations. For example, a hospital should not be able to "clone" a tertiary service whose quality is sensitive to volume (such as open-heart surgery) by splitting a single program into two or more parts. But for other services (hospital beds, emergency services, etc.) the issue is primarily one of economic feasibility, and the marketplace is quite capable of regulating that.

2. How can the CON Process Be Made More Efficient and Effective?

The MHA Work Group has pointed out several ways in which the CON process could be made more efficient and effective:

- Update the State Health Plan and keep it current
- Eliminate the use of standards not formally adopted in the State Health Plan
- Align the acute care bed need projections with the licensure law (which reflects market-focused health planning)
- Better define total available physical capacity and bed space
- Restrict completeness reviews to whether necessary application components are technically complete
- Be judicious about asking additional questions
- Streamline standards review through a "checklist" approach
- Encourage efficient construction by allowing shell space
- Create a "fast track" review process for certain projects
- Eliminate unnecessary redocketing

SMHC also advocates making the health planning process more efficient and effective by using a market-focused approach. For example, the health planning area which should be analyzed for determining the need for a new service proposed by an existing facility should not be an arbitrary area defined by political boundaries, such as a county or metropolitan area, but an actual market area such as the primary service area of the facility. This is a much better measure of the relevant geographic area.

Similarly, the need and potential demand for a new service proposed by an existing facility should be gauged, if possible, by the need/demand for a closely related service offered by that facility. For example, if a hospital applies for a CON for a neonatal intensive care unit ("NICU"), the need for NICU services could be evaluated by referring to the hospital's service area and volume of obstetrical services. Likewise, if a hospital applies for a CON for open-heart surgery, the need for the service could be evaluated by referring to the hospital's service area and volume of cardiology cases. This would allow the marketplace, as expressed by the demand for related services, to be a primary factor in planning for these specialized services.

3. How Can the Healthcare System Be Improved by Reducing Racial Disparities?

One of the most important issues facing America's healthcare system is the problem of racial disparities. See "Unequal Treatment – Confronting Racial and Ethnic Disparities in Health Care" (Institute of Medicine, 2002); "Racial/Ethnic Differences in Cardiac Care: The Weight of the Evidence" (Kaiser Family Foundation and American College of Cardiology Foundation, 2002); "2004 National Healthcare Disparities Report" (Agency for Healthcare Research and Quality, 2005).

While there are other bodies responsible for regulating costs and prices (the HSCRC, CMS, etc.) and for regulating quality of care (Office of Healthcare Quality, JCAHO, etc.), there is no other regulatory body in a position to influence racial disparities in healthcare in Maryland. The Maryland Health Care Commission should make the reduction of racial disparities in healthcare one of the key goals of the State Health Plan, and one of the key criteria by which it evaluates CON applications for new facilities and services. This, too, can be viewed as a form of market-focused health planning, because its purpose is to meet a need/demand for services that is not being adequately met, for complex social reasons. (Racial disparities in healthcare exist over and above the disparities caused by lack of health insurance and other financial reasons, as shown by many studies of the problem.)

The MHCC should focus on the racial and ethnic population areas which are receiving less than their fair share of services. It should reward applicants which propose to serve those areas, and encourage creative solutions to this persistent problem in American healthcare.

Thank you for the opportunity to comment on the CON process.

Very truly yours,

Michael J. Chiaramonte

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cc: Francis P. Chiaramonte, M.D.
Tim Miller